Considered - TMK

PATENT
Attorney Docket No.: A-72186
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Qi *et al*

Serial No. 10/804,762

Filing Date: March 19, 2004

For: *Specific Inhibition of Allorejection*

Examiner: KELLY, Robert M.

Art Unit: 1633

DECLARATION
Pursuant to § 1.132

The undersigned, Dr. Uwe Staerz, hereby declares as follows:

1. I received my Ph.D. in Immunology in 1986. A copy of my curriculum vitae is attached. I am employed by Isogenis, Inc., the assignee of the above-referenced application and currently serve Chief Scientific Officer of the company.

2. I have read and am familiar with the disclosure in the above-referenced application and have reviewed as well the Examiner's comments in his most recent office action mailed May 2, 2006. I understand that the Examiner is concerned about the level of CD8 alpha chain expression in the allograft tissues and how it correlates with the immune inhibitory effect. As described in more detail herein, our own data in a solid organ transplant model demonstrates that only a fraction of the allograft cells actually need express the CD8 alpha chain in order for the immune inhibitory effect to be achieved *in vivo*.

3. In the experiment described in the patent specification at Example 3, standard pancreatic islet purification protocols were used. Adenoviral veto vectors had been produced as Adenoviral (Type 5) vectors. They were replication-deficient due to a lack of the E1 region (DE1). Genes coded within the E3 region had also been deleted to avoid the down-regulation of the MHC class I molecules on infected cells. The Adenoviral veto vector mAdCD8 carried the mouse CD8 alphachain as transgene, whose expression was controlled by a CMV immediate early promotor/enhancer.